

FDA  
Dockets Management Branch (HFA - 305),  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

Docket No. **99D-4488** and **99D-4489**

It is outrageous that you are continuing to demand that sprout growers solve the problem of seed safety instead of putting that responsibility where it belongs - on the seed producers.

The FDA should establish guidelines for the production of seed intended for human consumption. The FDA, USDA or other applicable agency should certify the seed produced by farmers as is done with meat (i.e. Grade A).

Sprout growers will need to buy either seed certified for human consumption and/or certified organic seed and must be able to produce proof of certification upon demand. Until such time as the supply of safe seed reaches levels necessary to satisfy the demand, sprout growers should have the option of sterilizing their (not specifically intended for human consumption) seed and lab testing to assure absence of pathogens - as outlined in the guidance.

As you know the only currently safe source of seed is that which is Certified Organic. The FDA should contract the advice and help of certified organic seed farmers to establish methods which will make the conventional farming of seed for human consumption as safe as the certified organic method.

The FDA should add to the Guidance a clause which states that "Certified Organic as well as seed certified by FDA as for human consumption is considered an acceptable alternative approach to prevention of microbial hazards in sprouted seeds."

It is ridiculous to demand that all sprout growers have an in-house lab and that they use toxic levels of bleach (which is a known carcinogen and a terrible pollutant) on a long-term basis. Most sprout growers can not afford labs (and would therefore be forced to cease operations) and many - hopefully - know that the dumping of bleach for the sake of producing a health food is absolutely absurd - especially at the levels currently used and suggested in the guidance. Also, the lack of good bacteria in sterilized sprouts is a major loss to consumers. We are, after all, dependent on commensal bacteria!

By allowing sprout growers to use seed fit for human consumption the small growers can survive. The big growers will still have the option of buying any seed, as long as they fulfill the sterilization and lab testing requirements outlined in the guidance.

Sincerely,



Submit written comments **by December 13, 1999**, to ensure adequate consideration in preparation of revised documents, if warranted.

Identify as **Docket No. 99D-4488** and **99D-4489**

99D-4488 + 99D-4489

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THOMAS SALACH, M.D.  
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1228 '99 NOV 16 4:27  
Nov. 10, 1999

FDA  
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Rockville, MD 20852

Dear Madam/Sir:

I do not understand why every nook and cranny of the food chain must be adulterated in the quest for an absolute and chimeric safety. Will you not leave any room for the small players who wish to provide us with a natural and organic product as humanity through the ages has habitually consumed until the advent of agri-business. We are mature and well informed consumers, and in weighing the relative risks, we feel our choice is by far the wisest both for our health and that of our overly assaulted ecosystems. Please leave some room for reasonable and traditional alternatives.

Cordially,

Thomas J. Salach MD

A handwritten signature in black ink that reads "Thomas J. Salach MD". The signature is written in a cursive, flowing style.

CROSS FILE SHEET

File Number:

99D-4488/C *9*

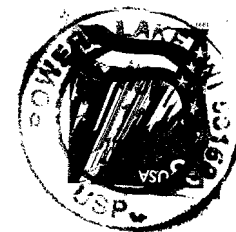
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99D-4489/C *9*

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